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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,075	03/16/2001	Carl Arne Krister Borrebacck	BIOT 100	6298

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/03/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,075

Applicant(s)

BORREBAECK ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-2, 4-9 and 11-13 are under examination.

Claims 3, 10 and 14-37 have been cancelled.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-9 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record.

Response to Arguments

Applicants rely on the Vas-Cath Inc. v. Mahurkar decision that states the patentee "recount his invention in such detail that his future claims can be determined to encompass within his original creation."

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Applicants argued that one skilled in the art would clearly understand what is meant by the terms "ligands", "library" and anti-ligand" of the present specification and technologies known at the time of filing the present application. It is further argued that replicable units are clearly defined at page 9, lines 14-20. It is further argued that each of the other terms is described in the specification.

In reply, as stated in the last Office action, the definition of each of the terms in the claims is not controverted. But the specification provides nothing more than these argued definitions of each of the claimed terms. What is controverted is the description of each of the claimed terms as generally claimed and defined. There is no explicit or specific description as to the employment of each of the generic definitions in the general method steps. As clearly stated in the Vas-Cath Inc. decision, the invention must be described in such details not just to list or define each of the already known terms. It is not apparent from the Examples whether a specific ligand/anti-ligand has actually been made. This is made more complex in view of applicants' statement at page 3, lines 20-29. It states ".....despite the potential benefits of methods of studying protein expression, the identification of proteins poses much greater problems than the identification of DNA. **Even**

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if the primary structure of a particular protein is known, knowledge of what molecules will specifically bind to the protein, and therefore serve as a probe for that protein, cannot be predicted....." (Emphasis added).

The generalizations made in the specification and a mere laundry lists of ligand and anti-ligand do not equate to an adequate description for the claim. The claim contains too numerous undefined or unknown variables.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-9 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

In view of the amendments to the claims the rejections under this statute no longer applies.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-9 and 11-13 are rejected under 35 U.S.C. 103(a) as being obvious over Wagner et al (6,329,209) in view of Stevens (USP 6,410,692) or applicants' disclosure of known prior art and Kwahli (USP 5,990,268).

Wagner discloses at col. 3, line 58 up to col.4, line 16 a method for producing an array of protein-capture agents(anti-ligand as broadly claimed) comprising a first step of selecting protein-capture agents from a library of protein-capture agents, wherein the protein-capture agents are selected by their binding affinity to proteins which are the expression products, or fragments thereof, of a cDNA expression library. The second step of the method comprises producing a plurality of purified samples of the protein-capture agents selected in the first step. The third step comprises immobilizing the protein-capture agent of each different purified sample onto an organic thin

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film on a separate patch on the substrate surface to form a plurality of patches of protein-capture agents on discrete, known regions of the surface of a substrate.

Wagner further discloses at col. 12, lines 9-40 that the binding partners of some or all of the protein-capture agents on the array need not necessarily be known. The binding partner of a protein-capture agent of the array may be a protein or peptide of unknown function. The different protein-capture agents of the array may together bind a wide range of cellular proteins from a single cell type, many of which are of unknown identity and/or function. Wagner teaches at col. 13, lines 6-35 that the protein-capture agents are antibodies or antibody fragments. The antibodies or antibody fragments of the array may optionally be single-chain Fvs, Fab fragments, Fab' fragments, Fv fragments, dsFvs diabodies, Fd fragments. The antibody fragments have been derived by selection from a library using the phage display method (step i, as claimed). The antibody fragments are derived individually by selection based on binding affinity to known proteins, wherein, the binding partners of the antibody fragments are known. The antibody fragments have been derived by a phage display method comprising selection based on binding affinity to the (typically, immobilized) proteins of a cellular extract or a body fluid (step ii, as claimed). In this respect,

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some or many of the antibody fragments of the array would bind proteins of unknown identity and/or function. The detailed method and components used in the method is presented in the Examples 1-7, col. 38 up to col. 44. Wagner does not expressly disclose the limitation of claimed step (iii) i.e., the ligands in the mixture are separated on the basis of structural characteristics selected from the group consisting of size, electrical charge and isoelectric point. However, Stevens discloses at e.g., col. 2, lines 41-59, that the removal of high abundant macromolecules from a liquid sample followed by a high resolution 2-D electrophoresis allows for visualization of low abundant sample proteins that might not be visualized with limits in total protein load. When the high resolution 2-D electrophoresis includes in-gel sample rehydration of immobilized pH gradient strips, followed by isoelectric focusing in the first dimension and SDS-PAGE in the second dimension, this method is called "High Capacity Two-Dimensional Polyacrylamide Gel Electrophoresis" ("HiCap 2-D PAGE"). HiCap 2-D PAGE permits relatively high amounts of low abundant proteins to be loaded following the removal of albumin and immunoglobulin. HiCap 2-D PAGE also permits the use of large sample load due to in-gel sample rehydration. The combination of abundant serum protein removal by the collapsible affinity

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matrix and HiCap 2-D PAGE produces highly reproducible maps of low abundance serum proteins in human serum. Applicants' disclosure at page 28, Example 3 discloses that "...antigens (ligands) in antigen preparations may be separated on the basis of differences in e.g., size, electrical charge or isoelectric point using e.g., size exclusion chromatography (see ref. 31), capillary electrophoresis (see ref 20).....Separation of complex mixtures of antigens utility any of the above technologies will give information of the identity of the antigens....." It would have been obvious to one having ordinary skill in the art at time the invention was made to separate the antigens in a mixture prior to reaction with an antibody in the method of Wagner for the advantages taught by Stevens above. The advantages taught by Stevens provide the motivations to one having ordinary skill in the art. Such separation is at the time of filing has been conventionally done in the art, as disclosed by the known references in the specification. It is also well known in the art that an important property of monoclonal antibodies is their specificity for single antigens (see Kwahli at col. 1, lines 25-27). [Note that Wagner also suggests that the antigen is filtered for separation prior to reaction with antibody. This presupposes separation by at least on the basis of size].

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

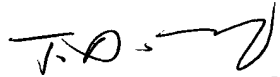
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
April 24, 2004